

Bonutti is directed to an expandable cannula that can include tethering cords that limit the expansion of the cannula. Bonutti has been discussed at length in the responses to prior Office Actions in this application and reference is made thereto. Briefly, the tethering cords of Bonutti extend from the cannula inner wall to the cannula outer wall. As the Examiner notes, Bonutti fails to show an array of filaments extending substantially from one end portion to the other end portion of the sheath. In order to remedy this deficiency, the Examiner asserts that it would have been obvious to include filaments taught by Fogarty in the cannula taught by Bonutti. Applicants respectfully disagree.

Fogarty is directed to a variable diameter sheath method and apparatus for use in body passages. A sheath 10 is elongate and proportioned to expand, when relaxed, to an outside diameter approximately equal to the inside diameter of the body passage within which the sheath is to be used. Fogarty, 3:27-32. In a typical embodiment, the sheath has an expanded relaxed diameter of from 6 to 7 mm and a contracted reduced diameter of 2 to 3 mm. *Id.*, 3:33-35. In short and as stated in Fogarty, “when in a passive state, the sheath assumes the expanded-diameter condition.” *Id.*, 2:22-25.

As an initial matter, Applicants respectfully submit that there would be no teaching, suggestion, or motivation to combine the references. Although the Examiner is correct in identifying that the filaments 42 of Fogarty reinforce the elastomeric coating 40, the filaments facilitate contraction and expansion of the sheath. *See id.*, 4:34-37. As stated in Fogarty, “[t]he filaments also serve to control expansion, contraction and the elongation of the sheath.” *Id.*, 4:37-38.

Bonutti teaches active cannulas that can vary in size and shape as needed. Thus, the cannulas taught by Bonutti are already expandable, without the addition of the filaments of Fogarty. One of ordinary skill in the art would not add filaments to the Bonutti cannulas. This is particularly true since Bonutti provides tethering cords that limit expansion of the cannula, and would also presumably provide reinforcement.

Even if one were to combine the references as suggested by the Examiner, the present invention would not be obtained. In one embodiment, a cannula 10 according to the present invention includes an expanding portion 12 with a plurality of wires 16 that are surrounded by an overlying elastic sheath 18. Specification, p. 7, lns. 15-20. The sheath 18 is of a diameter such that it is stressed even when the cannula is fully contracted. *Id.*, p. 8, ln. 27 to p. 9, ln. 1. “Thus the

sheath 18 constantly biases the wires 16 radially inwardly toward the axis 22 of the cannula 10.” *Id.*, p. 9, lns. 2-3. This is the exact opposite of Fogarty, in which there is a bias of the sheath and filaments to the expanded condition.

In order to clarify the differences between the claimed invention and the cited references, Applicants have amended independent claims 57 and 66 to recite that the sheath is biased in the contracted condition.

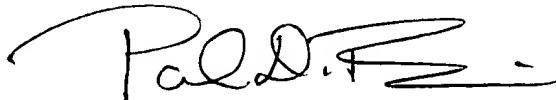
In light of the foregoing, independent claims 57 and 66 are respectfully submitted to be patentable over Bonutti and Fogarty, either alone or in combination. As claims 58-62, which depend from claim 57, and claims 67-71, which depend from claim 66, necessarily include all the elements of their respective base claim, Applicants respectfully submit that these claims are also allowable over the cited references at least for the same reasons.

Finally, Applicants acknowledge with appreciation the continued allowance of claims 64, 72, 73, 75, and 77-79.

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed to be due with this submission. However, please charge the required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 780-A02-003-2).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Paul D. Bianco", with a stylized flourish at the end.

Paul D. Bianco, Reg. # 43,500

Enclosures

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Marked-Up Copy of the Amended Claims

The identified claims were amended as follows, with additions underlined and deletions bracketed:

57. (Thrice Amended) An expandable cannula which is movable into a patient's body tissue, said cannula comprising a tubular sheath having a passage which extends between axially opposite end portions of said sheath, said sheath being resiliently expandable from a contracted condition in which the passage through said sheath has a relatively small cross sectional size in a plane perpendicular to a longitudinal central axis of said sheath to an expanded condition in which the passage through said sheath has a relatively large cross sectional size in a plane perpendicular to the longitudinal central axis of said sheath, said sheath having an oval cross section in a plane extending perpendicular to the longitudinal central axis of said sheath when said sheath is in the contracted condition; and an array of filaments which is enclosed by said sheath and extends axially substantially from one end portion to the other end portion of said sheath, wherein said sheath is biased in the contracted condition.

66. (Twice Amended) An expandable cannula which is movable into a patient's body tissue, said cannula comprising a tubular sheath which at least partially encloses an array of filaments which extends between axially opposite end portions of said sheath substantially from one end portion to the other end portion of said sheath, said sheath and said array of filaments being resiliently expandable from a contracted condition in which said sheath and said array of filaments have a relatively small cross sectional size in a plane perpendicular to a longitudinal central axis of said sheath to an expanded condition in which said sheath and said array of filaments have a relatively large cross sectional size in a plane perpendicular to the longitudinal central axis of said sheath, wherein said sheath is biased in the contracted condition.